REMARKS

I. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 stand rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection.

Applicants Present a Declaration which proves that Effervescent Tablets of the Cited Art Do Not Dissolve Orally in One Minute or Less

Effervescent tablets are not templates for the design of orally disintegrable tablets. The Shimizu Declaration which accompanies this response proves that when an effervescent tablet representative of the teachings of the Lundberg reference is ingested orally, it does not readily dissolve. Appendix A also accompanies this response. It contains a supplemental reference; which is the portion of the European Pharmacopoeia referenced on page 5 of the Declaration. Moreover, human subjects were not even able to keep the tablets in their mouths. As shown by the results of Table 7 of the Declaration, the volunteers were only able to keep the tablets in their mouths for about three minutes, after which time they had to spit them out as too uncomfortable. It was noted that even after three minutes, not even half of the tablet had disintegrated.

The cited art does not render the aspects of the present invention as set forth in independent claim 1 obvious because there is no teaching or suggestion of a tablet which is orally disintegrable in one minute or less in Lundberg (directed to multiple unit effervescent dosage forms), as proven by the Shimizu Declaration.

Applicants Indicate that the Second Component of their Invention is Neither Taught nor Suggested by the Cited Art

In independent claim 1, the second component of the orally disintegrable tablets is defined as a water-soluble sugar alcohol; in a certain amount, apart from the fine granules of the active substance. There is no teaching or suggestion of such component in the cited art.

Nor is there any teaching or suggestion of a sugar component apart from the active substance in the portions of the cited art referenced by the Examiner. In col. 8 cited by the Examiner, sugars are mixed with the active substance; while in col. 22, the sugar is part of the core material. Applicants do not believe that the cited reference teaches use of a water-soluble sugar alcohol which is present separately from fine granules of active substance.

Applicants Indicate that the Fine Granules of Their Tablets are Neither Taught Nor Suggested by the Cited Art

In independent claim 1, the fine granules are recited as having an average particle diameter of 400 microns or less; yet the cited art indicates a size of between 0.1 and 4 mm in col. 8. Claim 1 specifies fine granules because small granule size reduces roughness and oral discomfort; characterstics important for orally administered tablets. Since the tablets of the cited art were not designed to be ingested orally, the size of the formulated homogeneous core material is much larger. There is simply no teaching or suggestion of the presently claimed fine granule size in the cited art.

Applicants Show that the Examiner's Conclusions Regarding the Teachings of the Cited Art are Faulty

Applicants respectfully disagree with the Examiner's statement that the cited art teaches a disintegrating time of about 55 seconds. Yes, the reference shows that a 55 second time was recorded in the examples. But that time was an effervescence time as measured by dropping the tablet into a basket in a very large amount of water. The tablet effervescence time was not measured in a human, nor was the effervescence time measured in a test simulative of the conditions inside the human mouth.

The Examiner appears to acknowledge that the 55 seconds in the cited reference is not equivalent to Applicants' recited oral disintegration time of one minute or less elsewhere in her comments. Note that on page 4 of the Office Action mailed November 23, 2005, the Examiner plainly states that "Lundberg does not explicitly teach the oral disintegration time in one minute or less".

With respect to the statement found under point 4 at the top of page 7 and point 2 at the top of page 6 of the Office Action mailed November 23, 2005, the composition in the cited art refers to an active agent which is an acid-susceptible proton pump inhibitor. That means that it is acid-labile. If patients chew the effervescent tablets of the Lundberg reference, the enteric coating layer would be broken; and the acid-labile ingredient would be decomposed under the acidic conditions of the stomach. The multiple unit effervescent tablets taught by the cited art are designed for dissolution in water prior to ingestion. Those skilled in the art understand how such vehicles are administered; and the reasons why they are not chewed or swallowed with juice.

Furthermore, Applicants note that the Examiner's comments in the third paragraph, on page 7 of the Office Action mailed November 23, 2005 do not apply to the present application. The paragraph appears to have been copied from the Examiner's response in a different case, as four Declarations have not been filed in the present case.

Applicants do not believe that the aspects of their invention as set forth in independent claim 1 is rendered obvious by the cited art for the reasons provided above. Claims 2, 3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 depend upon claim 1. Applicants submit that the more specific dependent claims are also not rendered obvious for the same reasons.

Therefore Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Lundberg.

II. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg in view of Watanabe *et al.*

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 stand rejected as being unpatentable over Lundberg, (U.S. Patent No. 6,132,770), in view of Watanabe *et al.*, (Biol. Pharm. Bull. 1995 article). Applicants respectfully traverse the rejection.

Applicants have discussed Lundberg exhaustively in Sec. I above. Applicants hereby incorporate the arguments made in that section to this section.

Applicants have previously argued that one skilled in the art of pharmaceutical formulation would not look to a reference directed to effervescent tablets when designing rapidly orally disintegrable tablets. Applicants sustain their position.

Applicants also argue that the deficiencies of Lundberg are not cured by the teachings of Watanabe *et al.*, as Watanabe *et al.* neither indicates fine granules of having an average particle diameter of 400 microns or less; nor a water-soluble sugar alcohol apart from the fine granules. So even if the references were combined, they do not teach the Applicants' invention as set forth in independent claim 1.

Applicants do not believe that the aspects of their invention as set forth in independent claim 1 is rendered obvious by the combined teachings of the cited art for the reasons provided above. Claims 2, 3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 depend upon claim 1. Applicants submit that the more specific dependent claims are also not rendered obvious for the same reasons.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Lundberg *et al.* in view of Watanabe *et al.*

III. Discussion of the Additionally Cited Art

Applicants wish to thank the Examiner for bringing the cited art of Mizumoto *et al.*, Lattanzi *et al* and Makino *et al.* to their attention. Applicants have carefully reviewed these references and do not believe that they detract from the patentability of the subject invention.

IV. Conclusion

Reconsideration and allowance of the pending claims is requested in light of the arguments provided above. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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